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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/762,431 | 05/22/2001 | Shalaby Wahba Shalaby | 00537-183002 | 4602 |

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| EXAMINER |
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MITCHELL, GREGORY W

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,431

Applicant(s)

SHALABY ET AL

Examiner

Gregory W. Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08), Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Remarks and Amendments filed June 01, 2005. Claim 11 has been amended. Claims 11 and 12 are pending and are examined herein.

Applicant's amendment of "ε-caproic acid" to "ε-hydroxy caproic acid" is entered and found not to be new matter for the reasons set forth on page 13 of the Remarks dated June 01, 2005.

Applicant's amendments have necessitated the withdrawal of the 35 USC 103 rejections of the Office Action dated November 29, 2005. The following rejections now apply.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11-12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 and 12 recite the limitation "absorbable polyester". The broad portion of claim 11 has been amended such that the term "absorbable" has been deleted. Accordingly, there is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winner et al. (USPN 4487860) in view of Tess et al. (USPN 2729609).

Winner et al. teaches a composition for coating surfaces comprising an aqueous polyelectrolyte polymer intermixed with a phosphated polyester, in general (Abstract; col. 1, lines 9-17). Specific phosphated polyesters are taught to comprise dicarboxylic acids (e.g. phthalic acid, succinic acid, etc.), which are esterified with an excess of simple glycols (e.g. ethylene glycol, etc.). The terminal alcohols are then reacted with phosphoric acid to prepare a monophosphate resin. Winner et al. also teaches that small amounts of monocarboxylic acids can be used. See col. 5, line 66-col. 8, line 56.

Winner et al. does not specifically teach a phosphated polyester comprising one of the specific monomers recited in claim 11 of the instant Application.

Tess et al. teaches a surface coating composition comprising a polymer comprising a polybasic acid (e.g. phthalic acid, succinic acid, etc.), a polyhydric alcohol (i.e. a polyol or a glycol), a monocarboxylic acid, and an additional modifying agent (e.g. lactic acid) for non-drying alkyds (col. 1, line 15-col. 3, line 59).

It would have been obvious to one of ordinary skill in the art to modify the phosphated polyester of Winner et al. by adding lactic acid as a monomer component

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therein because (1) Winner et al. teaches phosphated polyesters, in general; (2) Winner et al. and Tess et al. are both drawn to compositions for coating surfaces; (3) Winner et al. and Tess et al. comprise similar components (i.e. dicarboxylic acids, polyols, and monocarboxylic acids); and (4) Tess et al. teaches that lactic acid is useful in such surface coating polymer compositions. One would have been motivated to utilize the lactic acid as a monomer in the compositions of Winner et al. because, as taught by Tess et al., such modifying agents are useful in preparing non-drying alkyds.

It is Examiner's position that Applicant's recitations of the "biodegradable" nature of the polyester claimed in the instant Application does not render the claims patentable because the "biodegradable" nature of the polyester is a property of said polyester. Accordingly, because Winner et al. in view of Tess et al. teaches the same polyester, it is Examiner's position that the particles rendered obvious by Winner et al. and Tess et al. will possess the properties claimed in claim 11. If the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). It has been held that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* of obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winner et al. and Tess et al. as applied to claim 11 above, and further in view of Kakizawa (USPN 5686540).

Winner et al. and Tess et al. apply as disclosed above. Winner et al. further teaches that small amounts of triethylene glycol can be used as the polyol for preparing the phosphated polyester taught therein (col. 8, lines 32-56). Neither Winner et al. nor Tess et al. specifically teaches a polyethylene glycol as a component of the polyesters taught therein. It is noted, however, that triethylene glycol is, at a minimum, an oligoethylene glycol segment and could, itself, be considered a polyethylene glycol segment.

Kakizawa teaches a lactic acid based polyester comprising a dicarboxylic acid component (e.g. phthalic anhydride, succinic acid, etc.) and a diol component (col. 4, lines 57-62). The diol component is taught to be either a small glycol, such as ethylene glycol, or a polyoxyalkylene, such as polyethylene glycol (col. 6, lines 36-53). Polyoxyalkylenes are taught to provide excellent flexibility (col. 6, lines 47-53).

It would have been obvious to one of ordinary skill in the art to substitute the simple glycol of the phosphate polyester rendered obvious by Winner et al. and Tess et al. with a polyethylene glycol because (1) Winner et al. teaches that triethylene glycols may be used in the invention taught therein; (2) Kakizawa is an analogous art to both Winner et al. and Tess et al. (each invention is drawn to a polyester comprising a dicarboxylic acid component and a diol component); and (3) Kakizawa teaches that polyoxyalkylenes, generally, and polyethylene glycols, specifically, are useful in

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polyesters comprising a dicarboxylic acid component and a diol component. One would have been motivated to modify the polyester rendered obvious by Winner et al. and Tess et al. in the manner described above because, as taught by Kakizawa, such a modification would provide excellent flexibility.

Response to Arguments

Applicant argues, "Examiner has failed to provide some suggestion of the desirability of doing what the Inventors of this application have done." This argument is not persuasive because, as discussed, above, Tess et al. teaches the modifying agents (e.g. lactic acid) disclosed therein as useful in preparing non-drying alkyds.

Applicant's arguments that Winner and Tess are not directed to the same subject matter are not persuasive because, as discussed above, both Winner et al. and Tess et al. are both drawn to compositions for coating surfaces. Applicant's argument that "the resins and blends of Winner and Tess used to coat cans and baking equipment would not 'have commended ... and inventor's attention' relevant to a polymer used for the controlled release of a bioactive agent in a pharmaceutical, and as such both references are not analogous to the teachings of the instant application and as such, the Examiner's 2nd point in his reasoning for combining Winner and Tess, i.e., that Winner and Tess are drawn to the same subject matter, is flawed" is not persuasive. It is noted that Examiner does not contend that Winner et al. and Tess et al. are of an analogous art to Applicant's invention, but to each other. Furthermore, it is pointed out that Applicant is arguing limitations that are not in the claims. The instant claims are

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directed to a polyester. No recitation of a bioactive agent, a pharmaceutical composition, etc. is indicated in the pending claims. Accordingly, it is Examiner's position that the polyester, as claimed, is obvious, for the reasons set forth above, over Winner et al., Tess et al. and Kakizawa.

With respect to Applicant's argument that Winner et al. is directed to a blend, Examiner again points out that the pending claims are directed, only, to a polyester and not to a pharmaceutical composition, etc. Accordingly, the polyester claimed may be present alone or in combination and still meet the pending claims.

Applicant argues, "there is a suggestion in Winner that not every chain is phosphorylated." This argument is not persuasive because Examiner does not agree with Applicant's perception of the teachings of Winner et al. Winner et al. at col. 7, lines 48-51, states that it is preferred that the phosphoric acid is not *coreacted*, indicating only that Winner et al. teaches away from the dimers. Accordingly, Examiner does not agree with Applicant's argument that "Winner does not recognize the benefits of the free -OH as implicitly required by claim 11." Furthermore, this teaching is consistent with Applicant's claim of a -O-P(O)(OH)₂ group per polyester.

Applicant's arguments that Tess et al. and Kakizawa do not remedy the deficiencies of Winner et al. are not persuasive because Examiner does not agree that Winner et al. possesses the deficiencies alleged.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

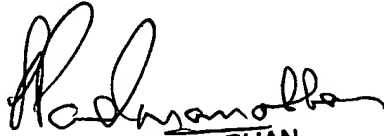
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm


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